K063519

510(k) summary

Dynamic Gas Scavenging System (DGSS™)

Submitter:

DEC - 1 2006

Anesthetic Gas Reclamation, LLC
700 Two American Center
3102 West End Avenue
Nashville TN 37203-1304
615-336-0963 (voice)

Contact:

James M Berry, MD

Date:

October 9, 2006

Device Name:

Dynamic Gas Scavenging System (DGSS™)
An interface valve for scavenging waste anesthetic gases

Classification Name:

Apparatus, Gas Scavenging

Product Code:

CBN

Regulation Number:

868.5430

Predicate Device:

K842003 - Ohio Waste Gas Scavenging Reservoir

Device Description:

The DGSS™ is a single unit, designed to replace a traditional anesthetic gas scavenging (interface) assembly, located between the exhaust outlet of an anesthesia machine and the waste anesthetic gas disposal (WAGD) suction line in an operating room. Like prior technology, it provides a safe interface between anesthesia delivery systems and hospital-provided WAGD suction lines.

The DGSS™ is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children.

The DGSS™ incorporates the same safety systems as predicate devices, providing relief of excess positive pressure and excess negative pressure to the patient through the use of "pop-off" relief valves, in compliance with ASTM 1343-02 – Anesthetic Equipment – Scavenging Systems for Anesthetic Gases.

Although the indications and intended use are identical with predicate devices, the DGSS™ replaces the manually-adjusted needle valve with an automatic mechanism regulating the flow in the WAGD suction line. This valve is controlled by a pressure-sensing switch which closes the valve when negative pressure is sensed in the manifold. This serves to reduce the needless entrainment of room air into the WAGD system of the healthcare facility. This sensor-valve arrangement operates within the inlet pressure range of -0.5 to 3.5 cm H2O, as specified by ASTM 1343-02

The valve-sensor mechanism is electrically powered with low-voltage direct current to prevent any hazard of electrical or fire injury in compliance with IEC 60601-1. The valve is normally open, so that a failure of electrical power results in the unit reverting to function identically to the predicate device. Other failure modes operate identically with the predicate device.

Although the electrical portion of the device section presents no hazard of spark or fire, additional protection is provided by physically separating the electrical system from the waste gas pathway. This isolates the electrical subsystem from exposure to any oxygen-enriched waste anesthetic gas.

Although technologically more advanced and efficient than the predicate device, the DGSS™ presents no additional issues of safety or efficacy due to its design. Any failure of the new design feature converts the device to one identical to predicate technology. Due to this design, the DGSS™ is substantially equivalent to the predicate device.

Additional detailed information is attached as a section entitled "Specifications."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Anesthetic Gas Reclamation, LLC
C/O Mr. Robert Mosenkis
Responsible Third Party Official
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

DEC - 1 2006

Re: K063519
Trade/Device Name: Dynamic Gas Scavenging System (DGSS™)
Regulation Number: 868.5430
Regulation Name: Gas-Scavenging Apparatus
Regulatory Class: II
Product Code: CBN
Dated: November 20, 2006
Received: November 21, 2006

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

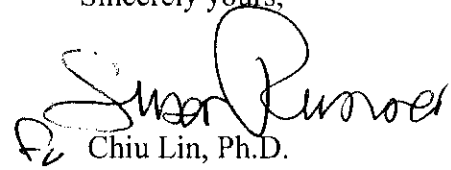
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: Dynamic Gas Scavenging System (DGSS™)

Indications for Use:

The DGSS™ is intended to be used for the scavenging of waste anesthetic gases from anesthesia machines used during the provision of general anesthesia to adults and children.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K063519